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PATIENT-REPORTED OUTCOMES IN STUDIES PUBLISHED IN 2014: WHICH TOOLS HAVE BEEN MOST COMMONLY USED IN STUDIES OF MUSCULOSKELETAL DISORDERS?

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OBJECTIVES: To determine which patient-reported outcome (PRO) tools were used in studies on musculoskeletal diseases published in 2014. **METHODS:** An evidence surveillance process was established based on a systematic search of PubMed, incorporating all studies published from 2010 and updated weekly, with a final search on 18 May 2015. Abstracts identified by the search that reported quality of life outcomes in musculoskeletal disorders were identified. Articles were included if they reported results or a study protocol from a primary research study or were a systematic review. PRO tools were identified from the abstract alone, where possible. **RESULTS:** The search identified 1,980 articles published in 2014. Of these, 197 (10%) were in musculoskeletal disorders. The most commonly researched diseases were osteoarthritis (19 articles), rheumatoid arthritis and back pain (14 each), fibromyalgia and fractures (10 each), and ankylosing spondylitis (9). Overall, 160 different PRO or clinician-reported instruments were cited in the 197 abstracts, with 93 articles citing more than one tool. Pain instruments were most commonly used (82 articles included either VAS or unspecified pain measurement). Utility measurement was made in 36 studies, with SF-36 used twice as often as either SF-12 or EQ-5D. PROs most commonly cited included WOMAC (13 articles), DASH (9), KOOS (9), HAQ (8), WHOQOL-BREF (6), FIQ and WOSI (5 each). The PRO used was not specified in 52 article abstracts: 22 of the 143 primary research articles, 7 of 18 study protocols and 30 of 34 systematic reviews. **CONCLUSIONS:** A wide range of musculoskeletal disorders were researched in 2014, with little overlap in PRO tools used even within diseases. Standardisation of tool use would aid comparison of outcomes across studies. Evidence surveillance including study protocols, results and systematic reviews may help identify trends in PRO use within specific diseases.

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PRO CLAIMS IN FIBROMYALGIA: A REVIEW OF THE LABELS OF PRODUCTS APPROVED BY THE FDA AND THE EMA

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OBJECTIVES: Fibromyalgia is a chronic pain syndrome characterized by increased sensitivity to pain, fatigue, muscle stiffness, difficulty sleeping, problems with mental processes (known as "fibro-fog"), such as problems with memory and concentration, headaches, and irritable bowel syndrome. The objectives of this study were 1) to identify patient-reported outcome (PRO) claims in products specifically approved for the treatment of fibromyalgia by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) since 1995, and 2) to identify the endpoint positioning of the PROs when measured. **METHODS:** The websites of the FDA and the EMA were explored to identify all products approved specifically for fibromyalgia. PROLabels was used to identify products with a PRO claim in label. All corresponding clinical reviews (FDA), and assessments reports (EMA) were reviewed to check for endpoint positioning. **RESULTS:** Since 1995, only three products have been approved with the specific indication of fibromyalgia (three by the FDA, i.e., duloxetine, milnacipran and pregabalin). None have been approved by the EMA. All of the products approved by the FDA include PRO claims in their label: reduction in pain, improvements in function, and in patient global impression of change (PGIC). When the medical review was available (duloxetine, milnacipran), the analysis of endpoint positioning showed that reduction in pain (either measured by the overall score of the Brief Pain Inventory or a Visual Analog Scale) was the primary efficacy endpoint. In one case (duloxetine), and for one study, the PGIC was also considered as a primary endpoint. Function was a secondary endpoint measured either by the Fibromyalgia Impact Questionnaire (duloxetine, pregabalin) or the SF-36 Physical Component Summary (milnacipran). **CONCLUSIONS:** PROs are essential to the evaluation of fibromyalgia products and are included in the labels of all products approved by the FDA. Reduction in pain is the key primary endpoint.

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UNDERSTANDING THE RELATIONSHIP BETWEEN HEALTH ASSESSMENT QUESTIONNAIRE-DISABILITY INDEX (HAQ-DI), PSORIASIS AREA SEVERITY INDEX (PASI), AND QUALITY OF LIFE (QOL) AND ITS INFLUENCE ON COST-EFFECTIVENESS IN PSORIATIC ARTHRITIS (PSA)

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OBJECTIVES: To evaluate the relationship between the disease activity measures (HAQ, PASI) and patient's QoL based on different utility mappings and its influence on cost-effectiveness (CE) **METHODS:** The identified algorithms of a literature research project that includes database screening of publications in English language from 1996-2015 have been extracted and the differences have been explored in a CE model for PsA. The model follows a decision tree for the first 12 weeks and Markov structure for rest of the time horizon with three month cycle length. **RESULTS:** The research retrieved 13 different algorithms to derive utilities in PsA patients based on clinical study data. In these studies, utilities were measured either with the SF-36 (n=5) or the EQ-5D (n=9) instruments. Different algorithms used different independent variables such as HAQ-DI, PASI or Disease Activity Score 28 (DAS28) to predict utility values. The arthritis component of the disease was measured either through HAQ-DI (n=11) or DAS28 (n=2), whereas PASI was used for the skin component (n=4). Most of the algorithms were using a linear approach (n=11). Among these linear algorithms one unit decrease of HAQ-DI improves patient's utility by 0.1 to 0.3 units. Effect of PASI on utility was much smaller as compared to HAQ-DI (0.004 improvement in utility per unit decrease in PASI). Using these algorithms, the incremental cost-effectiveness ratios (ICER) were calculated for each biologic versus standard of care. For each biologic ICERs coefficient of variation (standard deviation/mean) was approx. 17%. **CONCLUSIONS:** HAQ-DI is the key influencing variable in deriving utility values for PsA patients in the current algorithms. In biologic cost-effectiveness models, ICER is sensitive to the algorithms used. The analysis suggests that there may be a need of an improved algorithm to inform cost-effectiveness models for predicting utility more accurately. This may help the healthcare decision makers to make more informed decisions.

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THE ASSOCIATION BETWEEN DISEASE ACTIVITY AND QUALITY OF LIFE AMONG PATIENTS WITH ANKYLOSING SPONDYLITIS IN POLISH POPULATION

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OBJECTIVES: The aim of this study was to assess the disease activity and quality of life of patients with ankylosing spondylitis (AS) in Polish population. **METHODS:** On-line questionnaire survey was performed to obtain data on disease activity and the quality of life. We used Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and EQ-5D questionnaires with visual analogue scale (VAS). BASDAI score was obtained using on-line calculator. EQ-5D states were converted into utilities for European population. The Spearman's correlation was used to present the association between the disease activity and the quality of life. **RESULTS:** A total number of 66 questionnaires was obtained. Patients reported mostly the problems with general discomfort and morning stiffness represented by 8 points on BASDAI scale, followed by tiredness and neck pain represented by 7 points and other pain represented by 5 points. Almost 30% of patients reported that morning stiffness lasts longer than two hours. The mean BASDAI score was 5.87 (SD: 1.81). Of all patients, 68% reported some (highest reported state) problems with mobility, 47% with looking after himself. A lot (highest reported state) of problems with usual activities reported 4% of patients, a lot of pain and discomfort was reported by 13% of patients and with feeling worried by 6%. In all domains "some problems" was the most frequent answer resulting that the most common EQ-5D state was "22222". The mean utility was 0.52 (SD: 0.195) varied from 0 to 1. Patient reported visual analogue scale was 47 (SD: 26) varied from 0 to 100. BASDAI score was significantly correlated with utility (-0.635) and VAS (-0.620). **CONCLUSIONS:** Ankylosing spondylitis significantly reduces the quality of life. The higher the BASDAI score representing the higher disease activity and the lower the quality of life, reported as both EQ-5D utility and VAS.

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AVOIDABLE BURDEN AND UNMET NEED ASSOCIATED WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS TREATMENT: A CROSS-SECTIONAL EUROPEAN STUDY IN THE REAL WORLD SETTING

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OBJECTIVES: Non-radiographic axial spondyloarthritis (nr-axSpA) is an inflammatory arthritic disease characterized by sacroiliac joint inflammation. Studies indicate that nr-axSpA is a long-term chronic condition and can impose a considerable burden on the patients' physical function, impairment, and health-related quality of life. This analysis aimed to investigate whether elements of the burden associated with nr-axSpA are avoidable. **METHODS:** Data were from the 2014 nr-axSpA Disease Specific Programme, a cross-sectional, multi-national survey of patients and rheumatologists conducted in France, Germany, Italy, Spain and the UK. Rheumatologists completed forms containing patient demographics, clinical results and symptomology. Patients completed patient self-completions (PSCs) containing the Work Productivity and Activity Impairment questionnaire and EuroQoL-5D (EQ-5D-3L) with the visual analogue scale (EQ-VAS). Biologic treatment naïve patients considered eligible for biologics by the physician were compared to patients receiving biologics for ≥6 months. Observations were weighted to ensure findings were more representative of the patient population. The weight was applied to all percentages, means and standard deviations (SDs). Appropriate weighted univariate regressions were performed to test for significance. **RESULTS:** The analysis comprised of 310 patients (mean age 42.5±11.8 [SD], 74.8% male), with 123 biologic-naïve and 187 biologic-treated patients. Only 76 PSCs were completed in total. Compared to biologic-treated patients, biologic-naïve patients had greater overall work impairment (37.1% vs. 18.8%), presenteeism (27.6% vs. 15.8%) and activity impairment (31.4% vs. 22.5%). Additionally, more biologic-naïve patients were currently experiencing acute episodes (12.7% vs. 2.5%) and inflammatory back pain (69.5% vs. 38.5%) (all $p<0.05$). There were no observed differences between cohorts regarding mean EQ-5D utility score (0.81 vs. 0.82) or EQ-VAS (65.5 vs. 64.8). **CONCLUSIONS:** A potential unmet has been highlighted in nr-axSpA patient management, which could be due to restrictions upon physicians prescribing choices. Reducing the duration between diagnosis and biologic treatment prescription could potentially lessen the societal and clinical burden of nr-axSpA.

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BURDEN OF RESIDUAL SKIN AND JOINT DISEASE IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH BIOLOGICS

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OBJECTIVES: To describe residual skin and joint disease and health-related quality of life (HRQoL) in psoriatic arthritis (PsA) patients treated with biologics, and explore the impact of residual disease on HRQoL, work productivity, and switching therapies. **METHODS:** This was a retrospective analysis of 2013/14 US-EU5 Adelphi Real World cross-sectional survey data from dermatologists, rheumatologists, and PsA patients receiving biologics for ≥6-months. Outcomes included: EuroQol-5 Dimension (EQ-5D), Health Assessment Questionnaire Disability Index (HAQ-DI) (rheumatologists), PROMIS-HAQ) (dermatologists), Dermatology Life Quality Index